

As Introduced

132nd General Assembly

Regular Session

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S. B. No. 344

Senator Schiavoni

Cosponsors: Senators Thomas, Williams, Yuko

A BILL

To enact sections 3702.37, 3702.371, 3702.372,
3702.373, 3702.374, 3702.375, 3702.376,
3702.377, 3702.378, 3702.379, 3702.99, and
3702.991 of the Revised Code regarding the
operation of cryostorage facilities.

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BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 3702.37, 3702.371, 3702.372,
3702.373, 3702.374, 3702.375, 3702.376, 3702.377, 3702.378,
3702.379, 3702.99, and 3702.991 of the Revised Code be enacted
to read as follows:

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Sec. 3702.37. (A) As used in sections 3702.37 to 3702.379
of the Revised Code:

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(1) "Cryostorage facility" means a facility that stores
reproductive tissues intended for the treatment of infertility
or the preservation of fertility. "Cryostorage facility" does
not mean a facility that stores reproductive tissues only for a
scientific research or law enforcement purpose.

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(2) "Emergency" includes a blizzard, earthquake, fire,
flood, power outage, snowstorm, or tornado.

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- (3) "Reproductive tissues" means gametes, embryos, and 19
other reproductive tissues from a human source. 20
- (4) "Personnel" means all of the following: 21
- (a) An individual employed by a cryostorage facility in a 22
full-time, part-time, or temporary position; 23
- (b) An individual who works at a cryostorage facility due 24
to being referred to the facility by an employment service; 25
- (c) An individual who works at a cryostorage facility as 26
an independent contractor. 27
- (5) "Qualified contact" means a member of a cryostorage 28
facility's personnel who meets both of the following 29
requirements: 30
- (a) The personnel member must have completed training that 31
enables the personnel member to respond to a notification 32
provided under an external notification system required by 33
division (C) (2) of this section and take measures appropriate to 34
the situation, including, as necessary, transferring 35
reproductive tissues to a properly functioning cryostorage tank 36
and documenting the transfer. 37
- (b) The personnel member must reside at a location from 38
which the personnel member is able to arrive at the cryostorage 39
facility in not more than twenty-five minutes. 40
- (B) Each cryostorage facility shall comply with all of the 41
following requirements: 42
- (1) The cryostorage facility must be equipped with all of 43
the following: 44
- (a) Adequate ventilation systems; 45

- (b) A low oxygen alarm system; 46
- (c) Devices for monitoring the temperature, and levels of 47
liquid nitrogen, inside cryostorage tanks in use at the 48
facility; 49
- (d) An alarm system that meets the requirements specified 50
in division (C) of this section. 51
- (2) The monitoring devices required by division (B)(1)(c) 52
of this section must be checked in both of the following 53
manners: 54
- (a) Visually at least twice each day in person by 55
qualified personnel of the cryostorage facility during the 56
facility's regular business hours; 57
- (b) At least once each year by a qualified external 58
accrediting entity or inspection agency acceptable to the 59
department of health. 60
- (3) The monitoring devices required by division (B)(1)(c) 61
of this section must be connected to a backup power supply. 62
- (4) If an external backup generator is used for the backup 63
power supply required by division (B)(3) of this section, the 64
external backup generator must undergo preventative maintenance 65
and servicing by a third party at least once each year and an 66
embryology supervisor or laboratory director who is a member of 67
the cryostorage facility's personnel must review and document 68
the maintenance and servicing. 69
- (5) If an external power pack is used for the backup power 70
supply required by division (B)(3) of this section, the external 71
power pack must be checked at least once each week to ensure it 72
has sufficient charge and an embryology supervisor or laboratory 73

director who is a member of the cryostorage facility's personnel 74
must review and document the check. 75

(6) The alarm system required by division (B) (1) (d) of 76
this section must be tested as part of a quality control program 77
at least once each week. 78

(7) Each alarm system test required by division (B) (6) of 79
this section must be documented in the cryostorage facility's 80
records and an embryology supervisor or laboratory director who 81
is a member of the facility's personnel must review and sign the 82
test documentation at least once each month. 83

(8) Backups for cryostorage tanks in use at the 84
cryostorage facility must be available for immediate use at the 85
facility, including either of the following: 86

(a) At least one cryostorage tank that has a storage 87
capacity that is at least equal to the cryostorage tank that has 88
the largest storage capacity of the cryostorage tanks in use at 89
the facility; 90

(b) Available storage space in other cryostorage tanks at 91
the facility in an amount at least equal to the storage space 92
used by all samples of reproductive tissue stored in the largest 93
cryostorage tank in use at the facility. 94

(9) The cryostorage facility must have a valid contract 95
with another entity that provides for a properly functioning 96
cryostorage tank to be delivered to the facility as a loan not 97
later than forty-eight hours after a cryostorage tank in use at 98
the facility ceases to function properly. 99

(10) If a cryostorage tank in use at the cryostorage 100
facility ceases to function properly, the facility must do both 101
of the following until a properly functioning cryostorage tank 102

is delivered to the facility in accordance with division (B) (9) 103
of this section and placed into use at the facility: 104

(a) Manually fill the liquid nitrogen used for the 105
cyrostorage tank that has ceased to function properly; 106

(b) Manually maintain the temperature inside that tank 107
within a safe range. 108

(11) Before a cryostorage tank begins to be used to store 109
reproductive tissue at the cryostorage facility, all of the 110
following requirements must be met: 111

(a) The tank must undergo a documented validation process 112
to ensure that it functions properly. 113

(b) The validation process must include the taking of 114
direct measurements to assess how much of the tank's liquid 115
nitrogen is depleted over a preset duration. 116

(c) An embryology supervisor or laboratory director who is 117
a member of the facility's personnel must review and sign the 118
documentation of the validation process. 119

(12) Adequate amounts of liquid nitrogen used for 120
cryostorage tanks in use at the cryostorage facility must be 121
available at the facility at all times. 122

(13) Except as provided in division (D) of this section, 123
both of the following requirements must be met if the 124
cryostorage facility stores multiple samples of reproductive 125
tissues from the same client: 126

(a) If the facility stores five or more samples of 127
reproductive tissues from the same client, the samples must be 128
stored in separate cryostorage tanks. 129

(b) If the facility stores at least two but less than five 130
samples of reproductive tissues from the same client, the 131
facility must offer the client the option of having the samples 132
stored in separate cryostorage tanks subject to the client's 133
payment of an additional storage fee. 134

(C) An alarm system required by division (B) (1) (d) of this 135
section must meet both of the following requirements: 136

(1) The alarm system must be able to produce a signal 137
audible to individuals at the facility whenever at least one of 138
the following happens to a cryostorage tank in use at the 139
cryostorage facility: 140

(a) The temperature inside the tank rises above a preset 141
threshold or falls below a safe range. 142

(b) The level of liquid nitrogen inside the tank falls 143
below a safe range. 144

(c) The tank's mass changes in a manner indicating a 145
problem with the tank. 146

(2) The alarm system must include an external notification 147
system that provides for the notification of at least a primary 148
qualified contact and, if the primary qualified contact does not 149
respond to the notification, a secondary qualified contact 150
whenever the alarm system detects a problem specified in 151
division (C) (1) of this section. 152

(D) The requirement of division (B) (13) of this section 153
regarding multiple samples of reproductive tissue from the same 154
client does not apply to any reproductive tissue the cryostorage 155
facility stores on the day immediately preceding the effective 156
date of this section. 157

(E) In addition to being subject to a fine under division 158
(A) of section 3702.99 of the Revised Code, a cryostorage 159
facility shall refund to a client any out-of-pocket costs the 160
client has incurred in having reproductive tissues stored at the 161
facility if the reproductive tissue is made nonviable due to the 162
facility's failure to comply with any requirement of division 163
(B) of this section. 164

Sec. 3702.371. Each cryostorage facility shall require all 165
of its personnel whose duties include handling liquid nitrogen 166
to complete, before handling liquid nitrogen, safety training in 167
handling liquid nitrogen. 168

Sec. 3702.372. (A) Each cryostorage facility shall do all 169
of the following to avoid or mitigate the damage to, or 170
destruction of, reproductive tissues stored at the facility that 171
an emergency could cause or causes: 172

(1) Develop an emergency preparedness plan; 173

(2) Include as a component of the plan an automated system 174
for quickly notifying by telephone the facility's personnel who 175
work at the facility when there is an emergency at the facility; 176

(3) Distribute the plan to the facility's personnel who 177
work at the facility; 178

(4) Test the component of the plan required by division 179
(A) (2) of this section at least once each month; 180

(5) In a manner consistent with division (B) of this 181
section, require the facility's personnel who work at the 182
facility to participate at least once each year in a test 183
implementation of all other components of the plan; 184

(6) Contract with a third party for the emergency transfer 185

and storage of the reproductive tissues in accordance with the 186
plan. 187

(B) The role of each member of the cryostorage facility's 188
personnel in a test implementation of an emergency preparedness 189
plan under division (A) (5) of this section shall be consistent 190
with the personnel member's regular duties. The facility shall 191
review the results of each test to identify both of the 192
following: 193

(1) Impediments to the personnel member's abilities to 194
perform their assigned tasks under the plan; 195

(2) Improvements that should be made to the plan or its 196
implementation. 197

Sec. 3702.373. (A) Each cryostorage facility shall do both 198
of the following: 199

(1) If reproductive tissues stored at the facility are 200
transferred to another location due to an emergency, provide the 201
facility's clients who are affected by the transfer notice of 202
the transfer, the new location of the tissues, and the status of 203
the tissues not later than fourteen days after the transfer is 204
completed; 205

(2) If a client's reproductive tissues that are stored at 206
the facility are damaged or destroyed due to equipment failure, 207
provide the client notice of the damage or destruction not later 208
than one week after the facility learns of the damage or 209
destruction and document the damage or destruction in the 210
client's record. 211

(B) Each contract that a cryostorage facility enters into 212
with a client to store the client's reproductive tissue shall 213
include a provision that explains the facility's duty to provide 214

notice to the client under divisions (A) (1) and (2) of this 215
section. 216

(C) A cryostorage facility shall maintain in a client's 217
records the client's preferred method for receiving from the 218
facility the notices required by divisions (A) (1) and (2) of 219
this section. If the facility is unable to use a client's 220
preferred method of receiving a notice, the facility shall 221
attempt to provide the notice to the client through an 222
alternative method. 223

(D) A cryostorage facility shall document in a client's 224
record each effort the facility makes to provide the client 225
notice under divisions (A) (1) and (2) of this section and the 226
results of each such effort. 227

(E) A cryostorage facility that provides to a client a 228
notice required by division (A) (1) or (2) of this section shall 229
inform the client of other cryostorage facilities at which the 230
client may have reproductive tissue stored if the facility is 231
unable to continue to store the client's reproductive tissue and 232
the client wants to continue having the reproductive tissue 233
stored. At the request of the client and the client's payment of 234
a transfer fee, the facility shall promptly transfer the 235
client's records and reproductive tissues to any other 236
cryostorage facility the client chooses. 237

Sec. 3702.374. (A) Each cryostorage facility shall do all 238
of the following: 239

(1) Maintain both of the following: 240

(a) Records that enable the facility to identify each 241
client's reproductive tissues stored at the facility; 242

(b) Laboratory log books and other records of the proper 243

identification and disposition of all reproductive tissues 244
stored at the facility that identify all of the facility's 245
clinical and laboratory personnel who have handled the 246
reproductive tissues to which the log books and records pertain. 247

(2) Require a laboratory supervisor or director who is a 248
member of the facility's personnel to review and sign the log 249
books and other records required by division (A) (1) (b) of this 250
section at least once each month; 251

(3) Subject to division (B) of this section, copy the 252
records and log books required by divisions (A) (1) (a) and (b) of 253
this section not less often than required by rules adopted under 254
section 3702.379 of the Revised Code; 255

(4) Comply with all applicable state and federal laws 256
governing the confidentiality of client records, including the 257
health information privacy provisions of the "Health Insurance 258
Portability and Accountability Act of 1996," 42 U.S.C. 1320d et 259
seq. 260

(B) For the purpose of division (A) (3) of this section, 261
the copies of the records and log books required by divisions 262
(A) (1) (a) and (b) of this section may be digital copies, if the 263
digital copies are maintained on a secure web site accessible to 264
the cryostorage facility and backups of the digital copies are 265
made not less often than required by rules adopted under section 266
3702.379 of the Revised Code. Regardless of the form in which 267
the copies of the records and log books are maintained, the 268
copies shall be kept in a secure location that is neither a room 269
in which reproductive tissue is stored nor the same room in 270
which the original records and log books are maintained. 271

Sec. 3702.375. Each cryostorage facility shall report to 272

the department of health instances of compromised cryostorage 273
tanks and other events that adversely impact reproductive 274
tissues stored at the facility. The reports shall be made in 275
accordance with rules adopted under section 3702.379 of the 276
Revised Code. 277

Sec. 3702.376. Each cryostorage facility shall make a good 278
faith effort to obtain liability insurance coverage or a surety 279
or fidelity bond that meets standards established in rules 280
adopted under section 3702.379 of the Revised Code. A 281
cryostorage facility that is able to obtain such insurance or 282
bond shall obtain and maintain the insurance or bond. 283

Sec. 3702.377. Each cryostorage facility shall comply with 284
the director of health's enforcement authority under section 285
3702.378 of the Revised Code. 286

Sec. 3702.378. The director of health shall enforce 287
sections 3702.37 to 3702.377 of the Revised Code and the rules 288
adopted under section 3702.379 of the Revised Code. To enforce 289
those sections and rules, the director may do all of the 290
following: 291

(A) Inspect cryostorage facilities; 292

(B) Issue orders to secure compliance with the provisions 293
of sections 3702.37 to 3702.377 of the Revised Code and the 294
rules adopted under section 3702.379 of the Revised Code; 295

(C) Hold hearings, issue subpoenas, compel testimony, and 296
make adjudications; 297

(D) If the director has reason to believe that a 298
cryostorage facility has knowingly failed to comply with a 299
requirement of sections 3702.37 to 3702.377 of the Revised Code 300
or a rule adopted under section 3702.379 of the Revised Code, 301

report the suspected failure to the attorney general, a county 302
prosecutor, or other appropriate law enforcement official. 303

Sec. 3702.379. The director of health shall adopt rules in 304
accordance with Chapter 119. of the Revised Code as necessary to 305
enforce the requirements of sections 3702.37 to 3702.378 of the 306
Revised Code. 307

Sec. 3702.99. (A) A cryostorage facility shall be fined 308
one hundred dollars for each day that the facility fails to 309
satisfy a requirement of division (B) of section 3702.37 of the 310
Revised Code. 311

(B) A cryostorage facility shall be fined five hundred 312
dollars for each of the facility's personnel who do not complete 313
the safety training in handling liquid nitrogen as required by 314
section 3702.371 of the Revised Code. 315

(C) A cryostorage facility shall be fined five hundred 316
dollars for the first day that the facility fails to satisfy a 317
requirement of section 3702.372 of the Revised Code and one 318
hundred dollars for each subsequent day that the facility 319
continues to fail to satisfy the requirement. 320

(D) A cryostorage facility shall be fined five hundred 321
dollars for each requirement of section 3702.373 of the Revised 322
Code that the facility fails to satisfy. 323

(E) A cryostorage facility shall be fined one thousand 324
dollars for each requirement of section 3702.374 of the Revised 325
Code that the facility fails to satisfy. 326

(F) A cryostorage facility shall be fined one thousand 327
dollars for each report it fails to make under section 3702.375 328
of the Revised Code. 329

(G) If a cryostorage facility is able to obtain liability insurance coverage or a surety or fidelity bond for the purpose of section 3702.376 of the Revised Code, the facility shall be fined one thousand dollars for each day that the facility does not have the liability insurance coverage or surety or fidelity bond. 330 331 332 333 334 335

(H) A cryostorage facility shall be fined one hundred dollars the first time it fails under section 3702.377 of the Revised Code to comply with the director of health's enforcement authority under section 3702.378 of the Revised Code and five hundred dollars each subsequent time it so fails. 336 337 338 339 340

Sec. 3702.991. All fines collected under section 3702.99 of the Revised Code shall be deposited into the infant vitality fund which is hereby created in the state treasury. The department of health shall use all money in the fund to support a program addressing infant mortality in this state. The program shall have both of the following features: 341 342 343 344 345 346

(A) A multipronged, population health approach to the issue of infant mortality which may include any of the following: 347 348 349

(1) Increasing awareness; 350

(2) Supporting data collection; 351

(3) Supporting analysis and interpretation to inform decision making and ensure accountability; 352 353

(4) Targeting resources where the need is greatest; 354

(5) Implementing quality improvement science and programming that is evidence based or based on emerging practices. 355 356 357

<u>(B) Measurable intervention activities regarding infant</u>	358
<u>mortality which may include activities related to any of the</u>	359
<u>following:</u>	360
<u>(1) Safe sleep;</u>	361
<u>(2) Community engagement;</u>	362
<u>(3) Centering pregnancy;</u>	363
<u>(4) Newborn screening;</u>	364
<u>(5) Safe birth spacing;</u>	365
<u>(6) Gestational diabetes;</u>	366
<u>(7) Smoking cessation;</u>	367
<u>(8) Breastfeeding;</u>	368
<u>(9) Care coordination;</u>	369
<u>(10) Progesterone.</u>	370